REQUEST FOR RECONSIDERATION

Claims 1-8, 10 and 11 are active in the case.

The rejection of Claims 1-9 under 35 U.S.C. §103(a) as unpatentable over Lehmann et al in view of Vetter et al is traversed.

Lehmann et al fail to teach or suggest that the copolymer melt used in the production by injection molding of pharmaceutical delivery coatings or capsules is devolatilized in a thermoplastic state. Vetter et al do not remedy the deficiencies of Lehmann et al, because Vetter et al describe a chemical reaction process in which a plastic melt, such as, polymethylmethacrylate is reacted with a treatment agent, such as, ammonium or amines to form poly(methacrylalkylimide) plastics. The mixtures of Vetter et al also do not contain a mold release agent as in the present claims. Further, the quality requirements for the moldings produced in Vetter et al are not comparable to those required for injection molded articles, i.e., capsules used for pharmaceutical purposes, as in the present invention. Thus, Vetter et al is not combinable with Lehmann et al, because it is outside the technical field of the present invention, i.e., the production of injection molded articles for pharmaceutical purposes and the moldings and method of filling the molded articles with an active pharmaceutical ingredient, as in the present claims, along with the above-mentioned fact that Vetter et al do not teach a mold release agent as necessary, as is the case with the present invention and Lehmann et al.

Finally, Vetter et al mention the possibility in column 3, lines 29-37 of removing treatment agents which do not react with the plastic. Vetter et al state in the above-mentioned section that water can be added as a carrier agent for the removal of residual monomers from polymethylmethacrylate. However, in Vetter et al, water must be added positively. In contrast, the present invention teaches how to produce high quality moldings for

pharmaceutical purposes and one important aspect in the production is the removal of low-boiling constituents, for instance, water, which is always present by passive uptake from the environment. Thus, since Lehmann et al did not recognize the problems involved with passive uptake of water from the environment during the production of injection moldings for pharmaceutical purposes, the worker of ordinary skill in the art would not be directed from Lehmann et al to Vetter et al, because the water removal in Vetter et al is for a different reason than the present invention, i.e., removal of positively added water for carrying away residual monomer and not from passive uptake of water from the environment. Thus, there is no motivation for the worker of ordinary skill in the art to adapt the devolatilization step of Vetter et al to the process of Lehmann et al.

Superior results are shown for injection moldings produced by the process of the present claims, as compared to injection moldings produced by processes outside the present claims. Example 1 uses a mold release agent within the amount range of the present claims and produces moldings by the process of the present claims which, after 300 injection molding cycles, produce no deposits on the surface of the mold used. The polished mold surface after 300 injection molding cycles is shiny and metallic, with high gloss. In contrast, in Comparative Example 2 in which the same monomers were used and the same process was carried out as that of Example 1 and very close to Examples 1 and 8 of Lehmann et al, in which there is used a mold release agent in an amount outside the range of the present claims, it was found that after only 14 injection molding cycles, matt areas could be found on the surfaces of the capsules produced. The injection mold was inspected after the 14 injection molding cycles and showed deposit on the surface of the mold. The deposit was analyzed and the presence of glycerol monostearate was detected. Finally, Comparative Example 3 in which the composition of Example 1, including a mold release agent within the amount range

of the present claims, was used, but the process had no devolatilization step, as in the present claims. The injection molding process of Comparative Example 3 with no devolatilization step produced capsules that had surface defects, such as streaks, grooves and uneven areas. Therefore, it is clear that the process of the present claims, which includes a devolatilization step and a mold release agent from 0.1 to 3% by weight, produces molded articles, such as, capsules for pharmaceutical purposes, superior to those produced by a process not including the devolatilization step of the present claims or having a mold release agent outside the percent by weight range of the present claims. Therefore, the claims distinguish over the combination of references.

It is submitted that Claims 1-8, 10 and 11 are allowable and such action is respectfully requested.

Respectfully submitted,

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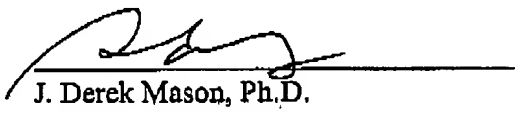

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MARKED-UP COPY OF AMENDMENT

IN THE CLAIMS

--1. (Amended) An injection moulding process comprising: [Process,]

[the steps in the process being]

A) Melting a mixture [made from] comprising

h) a (meth)acrylate copolymer [composed of] comprising from 40 to 100% by weight of free-radical-polymerized C_1-C_4-alkyl esters of acrylic or methacrylic acid and from 0 to 60% by weight of (meth)acrylate monomers having an anionic group in the alkyl radical, [where the copolymer comprises] and

i) from 0.1 to 3% by weight of a release agent,

and, [where appropriate] optionally, [the mixture may comprise]

j) from 0 to 50% by weight of a drier,

k) from 0 to 30% by weight of a plasticizer,

l) from 0 to 100% by weight of additives or auxiliaries,

m) from 0 to 100% by weight of an active pharmaceutical ingredient,

n) from 0 to 20% by weight of another polymer or copolymer,

[where] wherein the amounts given for components b) to g) are based on the (meth)acrylate copolymer a), and wherein

the mixture prior to melting has a content of more than 0.5% by weight of low-boiling constituents with vapour pressure of at least 1.9 bar at 120°C,

B) Devolatilizing the mixture in the thermoplastic state at a [temperatures] temperature of at least 120°C, thereby lowering to not more than 0.5% by weight the content of the low-boiling constituents with vapour pressure of at least 1.9 bar at 120°C,

C) Injecting the molten and devolatilized mixture into the mould cavity of an injection mould, the temperature of the mould cavity being below the glass transition temperature of the (meth)acrylate copolymer by at least 10°C, cooling the molten mixture, and removing the resultant moulding from the mould.

2. (Amended) [Process] The process according to Claim 1, [characterized in that] wherein the devolatilizing step [b]B) [takes place by way of] is carried out by extrusion drying by [means of] an extruder with a devolatilizing section, or by [way of] an injection moulding plant with a vent in the injection moulding cylinder upstream of the injection mould.

3. (Amended) [Process] The process according to Claim 1, [characterized in that] wherein the (meth)acrylate copolymer comprises, as (meth)acrylate monomer having an anionic group in the alkyl radical, from 1 to 50% by weight of methacrylic acid.

4. (Amended) [Process] The process according to Claim 1, [characterized in that] wherein the mixture comprises from 0.5 to 25% by weight of plasticizer.

5. (Amended) An injection moulding [which can be] produced by a process according to Claim 1.

6. (Amended) [Moulding] The moulding according to Claim 5, [characterized in that its] wherein the impact strength to ISO 179 is at least 5 kJ/m^2.

7. (Amended) [Moulding] The moulding according to Claim 5, [characterized in that it is] wherein the moulding comprises a capsule, part of a capsule, or part of a dosage unit.

8. (Amended) [Moulding] The moulding according to Claim 5, [characterized in that

it] wherein the moulding comprises an active pharmaceutical ingredient.

9. (Cancelled).

10-11. (New).--